

# News and Hot Topics

## Novelties in the regulation of animal experimentation in Spain

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This manuscript summarizes the innovations introduced in Spain concerning the applicable basic standards for the protection of animals used in experimentation and other scientific purposes, including teaching. The Royal Decree 53/2013 (henceforth RD53/2013)<sup>1</sup>, published on 1<sup>st</sup> February 2013, replaces the previous existing Royal Decree 1201/2005<sup>2</sup> of 10<sup>th</sup> October 2005. This law is transposition of Directive 2010/63/EU of the European Parliament and the Council of the European Union of 22<sup>th</sup> September 2010, and it includes some modifications on the protection of animals used for scientific purposes<sup>3</sup>.

The new rules are more demanding, both in the treatment to be dispensed to animals and in the bureaucratic controls to monitor that animal experimentation is being conducted under the new rules.

Regarding to the greater protection of animals, RD53/2013 reiterates the need to replace the use of live animals by other alternative approaches not entailing the use of them<sup>4</sup>, a notion which was already included in the Royal Decree 1201/2005. It also insists on reducing the use of animals to what is really needed. To this end, the ratio of expected benefits of research and inflicted damage on animals should be assessed<sup>5</sup>, and animals may only be employed when such use is justified by the intended purpose.

The RD53/2013 indicates more specific and refined details on the authorized methods for killing an animal<sup>6</sup>, and it establishes a new classification of severity of procedures<sup>7</sup> (under the previous, more indicative classification, the decision was left more to the ethics committee).

Similarly, the required animal housing conditions have changed. The Royal Decree 1201/2005 established the minimum conditions of the habitat for the animals. The minimums were raised in the Directive 2010/63/UE, and the RD53/2013 transcribes them<sup>8</sup>. Since these rules involve changes and investment in laboratories and animal facilities, a transition period is set, and the new specifications will be enforceable from 1<sup>st</sup> January 2017.

RD53/2013 has a bigger administrative control than the Royal Decree 1201/2005 with several manifestations.

The authorization of research projects involving the use of animals is now always dependent on public administration. Specifically, the “Competent Au-

thority”<sup>9</sup>, which is usually a department of the Ministry of Agriculture of the Autonomous Community (responsibility for animals has been transferred to Autonomous Communities).

The Animal Experimentation Ethics Committee and related entities may be designated as “Empowered body” when determined by the competent authority, and they are allowed for the initial project evaluation. Once evaluated, the empowered body must submit its opinion to the competent authority, which is the only entity that can authorize the use of animals. In addition, whenever required, the empowered body will perform a retrospective evaluation of projects and will transmit the result to the competent authority.

Previously, only projects qualified as “severe / prolonged” had their authorization referred to the public administration. Now, only a few activities with animals are excluded from the scope of this RD53/2013. Examples of such practices are “practices with animals not likely to cause them pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice”<sup>10</sup>; euthanasia of animals if performed with the sole purpose of using their organs or tissues<sup>11</sup>; the breeding of animals whose phenotypic characteristics do not involve noteworthy suffering<sup>12</sup>; or the manipulations aimed for the primary purpose of identification of an animal<sup>13</sup>.

When submitting the relevant documentation of a project to the competent authority for authorization, a non-technical summary, which it was introduced for first time in Directive 2010/63/EU and it is now reflected in RD53/2013<sup>14</sup>, should be included. This non-technical summary should be anonymous and it should not violate proprietary rights or expose confidential information of the project<sup>15</sup>. This will be made publicly available to ensure “social information” of the research being performed on animals. In theory, this information will enable society to get an idea of what is researched with animals so that the public can assert its voice if flagrant abuse is reported.

Inspection functions were also included in the RD53/2013<sup>16</sup>. The empowered body will periodically inspect animal research that falls under its jurisdiction, and the competent authority will also regularly

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inspect the user centre. Furthermore, the competent authority itself will be inspected by superior administrative authorities, and there will be periodic controls by the European Commission.

Finally, the RD53/2013 states that all projects must have a responsible person for the execution of the procedures<sup>17</sup>. It also indicates that the people involved in handling animals must have adequate capacity<sup>18</sup>. To this end, the categories for the manipulation of animals<sup>19</sup>, which were established under the Royal Decree 1201/2005 law, should be replaced by new rules on personnel training. These new norms will focus on training for specific procedures involving animals, maintaining meanwhile the validity of the previous manipulation categories<sup>20</sup>.

These changes are forcing researchers to better specify the details of their research in their projects. In addition, researchers need to be educated about

the new rules demanded by RD53/2013, which affect their projects from beginning to end. The increase in bureaucracy and stringency of requirements has raised protests from researchers. However, the drafting stage of the Directive 2010/63/EU, when opinions and suggestions were invited, has now elapsed. It has been suggested that the degree of control and the comprehensiveness of the new legislation indicate that animal rights groups exerted stronger pressure than responsible researchers and laboratories concerned with appropriate protection of animals.

- 1 Official text available in <http://www.boe.es/boe/dias/2013/02/08/pdfs/BOE-A-2013-1337.pdf>
- 2 Official text available in <http://www.boe.es/boe/dias/2005/10/21/pdfs/A34367-34391.pdf> For a review of the basic ethical questions of the animal experimentation, and a brief summary of this Royal Decree and their antecedent legislation, it can be seen Pardo A. Ética de la experimentación animal. Directrices legales y éticas contemporáneas. Cuadernos de Bioética 2005; 16(3): 393-417. Available in <http://www.aebioetica.org/revistas/2005/16/3/58/393.pdf>
- 3 Official text in Spanish available in <http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:ES:PDF> and in English available in <http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>
- 4 Article 2, a), of the Royal Decree 53/2013.
- 5 Article 34, 1, a) and b), of the Royal Decree 53/2013.
- 6 Annex III of the Royal Decree 53/2013.
- 7 Annex IX of the Royal Decree 53/2013, that establishes three degrees of severity of the procedures: light, moderate and severe.
- 8 Annex II of the Royal Decree 53/2013.
- 9 Article 3, 1, d), of the Royal Decree 53/2013.
- 10 Article 2, 5, f), of the Royal Decree 53/2013.
- 11 Article 3, 1, f), of the Royal Decree 53/2013.
- 12 Annex IX, section III, 1, h), of the Royal Decree 53/2013.
- 13 Article 2, 5, e), of the Royal Decree 53/2013.
- 14 Articles 33, 1, and 36, of the Royal Decree 53/2013.
- 15 The official explanation for the non-technical summary, a template, and sample of the content, are available in [http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/Recommendations%20for%20NTS.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Recommendations%20for%20NTS.pdf)
- 16 Chapter VII of the Royal Decree 53/2013.
- 17 Article 32, 3, of the Royal Decree 53/2013.
- 18 Article 15 of the Royal Decree 53/2013.
- 19 A, for animal care, B, for the execution of procedures, C, for the design process, and D, to those skilled in animal welfare.
- 20 Transitional provisions fourth and fifth of the Royal Decree 53/2013.